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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/948,149	10/09/97	FENDLY	B P1053R2

024510 HM12/0323  
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EXAMINER

SWARTZ, R

ART UNIT

PAPER NUMBER

1645

DATE MAILED:

03/23/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
**08/948,149**

Applicant(s)  
**Fendly et al**

Examiner  
**Rodney P. Swartz, Ph.D.**

Group Art Unit  
**1645**



☒ Responsive to communication(s) filed on 10 January 2001

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 28-40 and 42-58 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 28-40 and 42-58 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 21

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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### DETAILED ACTION

1. Applicants' Response to Office Action, received 10 January 2001, paper #25, is acknowledged. Claims 28, 32, 34, 42, and 58 have been amended.
2. Currently, claim 28-40 and 42-58 are pending and under consideration.

### Rejections Maintained

3. The rejection of claims 28-31, 37-38, 40, and 56, and 57 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Shepard et al (*J. Clin. Immunol.*, 11(3):117-127, 1991) is maintained.

Applicants argue that Shepard et al does not anticipate or render obvious the claimed invention, i.e., a method for inducing cell death comprising exposing a cell which overexpresses ErbB2 to an effective amount of an isolated antibody that cross-blocks binding of antibody 7C2 or antibody 7F3 to ErbB2.

Applicants argue that Shepard et al does not enable antibodies 7F3 and 7C2 or teach an isolated antibody that cross-blocks binding of antibody 7C2 or antibody 7F3 to ErbB2.

The examiner has considered applicants' argument, but does not find it persuasive. Shepard et al reference the procedure for making the antibodies as reference 28. In addition, the instant specification does not teach the claimed criticality of "an isolated antibody that cross-blocks binding of antibody 7C2 or antibody 7F3 to ErbB2". The section in the specification cited by applicants in support of their argument is page 6, lines 2-8 which recites "Preferably, the antibodies will bind to the ErbB2 epitope bound by the 7C2 and/or 7F3 antibodies described

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herein.” Figure 2 is the only instance of such competitive binding, and that shows only that 7C2 blocks itself as the legend of the figure indicates that the antibody treatment is “none”, “7C2-FITC”, “7C2 + 7C2-FITC”, and “4D5 + 7C2-FITC”. No other antibodies are shown. Thus, the statement on page 6 constitutes merely an invitation to experiment.

Applicants argue that Shepard et al neither teaches nor suggests that the disclosed antibody is “isolated”.

The examiner has considered applicants’ argument, but does not find them persuasive. “Isolated” antibody is defined in the instant specification as an antibody identified and separated/and or recovered from a component of its natural environment. The antibodies 7C2 and 7F3 are called monoclonal, which by definition means that they are “identified and separated/and or recovered from a component of its natural environment”.

4. The rejection of claims 28-31, 37-38 and 40 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lewis et al (*Cancer Immunol. Immunother.*, 37:255-263, 1993) is maintained.

Applicants argue that Lewis et al do not enable the particular antibodies 7F3 and 7C2.

The examiner has considered applicants’ argument, but does not find it persuasive for identical reasons as discussed above for Shepard et al. Lewis et al teach monoclonal anti-HER2 monoclonal antibodies, e.g., 4D5, 7C2, and 7F3, which inhibit human tumor cells such as SKBR3 (Table 2) and mediate antibody-dependent cellular cytotoxicity (Figure 4).

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5. The rejection of claims 32-36, 39, and 58 under 35 U.S.C. 103(a) as being unpatentable Shepard et al (*J. Clin. Immunol.*, 11(3):117-127, 1991), or Lewis et al (*Cancer Immunol. Immunother.*, 37:255-263, 1993), in view of Fendly et al (*Cancer Research*, 50:1550-1558, 1990), Deshane et al (*J. Invest. Med.*, 43(Suppl 2):328A, 1995), and further in view of Senter et al (U.S. Pat. No. 4,975,278) is maintained.

Applicants argue that Lewis et al do not enable the particular antibodies 7F3 and 7C2.

The examiner has considered applicants' argument, but does not find it persuasive for identical reasons as discussed above for Shepard et al. Fendly et al teach the production and characterization of the monoclonal anti-HER2 antibodies utilized by Shepard et al and Lewis et al (Abstract; page 1550-1552, section **Materials and Methods**).

6. The rejection of claims 42-55 under 35 U.S.C. 103(a) as being unpatentable over Shepard et al (*J. Clin. Immunol.*, 11(3):117-127, 1991), in view of Lewis et al (*Cancer Immunol. Immunother.*, 37:255-263, 1993) and Fendly et al (*Cancer Research*, 50:1550-1558, 1990), and further in view of Deshane et al (*J. Invest. Med.*, 43(Suppl 2):328A, 1995) and Senter et al (U.S. Pat. No. 4,975,278) is maintained.

Applicants argue that none of the cited references enable the particular antibodies 7F3 and 7C2.

The examiner has considered applicants' argument, but does not find it persuasive for identical reasons as discussed above for Shepard et al, Lewis et al, and Fendly et al.

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The examiner notes that applicant argues that "Hudziak et al" do not enable the instant antibodies. The examiner wishes to know what reference applicant is calling "Hudziak et al" as no reference by this name has been used in the rejections.

**New Rejections Necessitated by Amendment**

**Claim Rejections - 35 USC § 112**

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 28-39 and 42-58 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for antibody 7C2 blocking 7C2 + FITC binding, does not reasonably provide enablement for all other antibodies which cross-block binding of antibody 7C2 or antibody 7F3 to ErbB2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The claims are drawn to antibody which "cross-blocks binding of antibody 7C2 or antibody 7F3 to ErbB2". Page 6, lines 2-8 recites "Preferably, the antibodies **will** bind to the ErbB2 epitope bound by the 7C2 and/or 7F3 antibodies described herein.". Figure 2 is the only instance of such competitive binding, and that shows only that 7C2 blocks itself as the legend of

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the figure indicates that the antibody treatment is "none", "7C2-FITC", "7C2 + 7C2-FITC", and "4D5 + 7C2-FITC". No other antibodies are shown. Thus, the statement on page 6 constitutes merely an invitation to experiment.

### Conclusion

9. No claims are allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CAR 1.136(a).

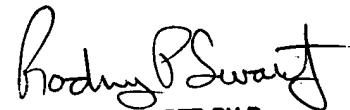
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CAR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4:00 PM EST.

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If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-0196.

  
RODNEY P SWARTZ, PH.D  
PRIMARY EXAMINER  
Art Unit 1645

March 23, 2001